FDA allows controversial new pigment to make drugs sparkle

By Kirsty Barnes

27/07/2006 - **In a controversial move, the US Food and Drug Administration (FDA) has given the final nod of approval to pharma companies who want to add colourful pearlescent pigments to their drugs to give them that *"special something."***

EXHIBIT A

Pearlescent pigments that can produce sparkly metallic, satiny and shimmery finishes can now be used in any drugs that are swallowed, including pills, capsules and liquids.

EMD Chemicals - part of part of German drug giant Merck – have developed the pigments by coating the mineral mica with either synthetic iron oxide or titanium dioxide.

The new FDA ruling signals the first time that mica can be used in an injestible drug and also increases the amount of iron oxide that can be used in such products – the use of titanium dioxide is already permitted.

Such pigments have long been used in makeup, including lipstick, eye shadow and nail polish, as well as in inks and automotive paint and even contact lenses and EMD has been asking the FDA for eight years to also allow their use in pharmaceuticals.

EMD now hopes to sell its pigments to drug companies who want to "glamorise" their drug products in order to claw back some kind of brand definition from the myriad of generic products bombarding the industry.

However, the thought of such pigments being used in medicines purely for cosmetic purposes has sparked a great deal of concern and outrage from consumer groups who believe that drugs should not be tampered with in this way.

The FDA first published its initial ruling on the matter on July 22, 2005 and immediately received a formal objection to the ruling on three grounds: that the pearlescent pigments would have iron salt contaminants; that these iron contaminants would cause stability issues for active pharmaceutical ingredients (APIs) and could interfere with drug efficacy; and that the use of iron-containing pearlescent pigments simply to colour drugs would limit the availability of medications for those who are monitoring their iron intake.

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In response, the FDA conducted a one-year assessment and last week reiterated its initial decision, stating: *"the agency has concluded that the objections do not raise issues of material fact."*

Under it's ruling, the FDA has said the pigments can make up no more than three per cent of a drug's weight.

The FDA maintains that *"the bioavailability of these pigments and/or their individual components when ingested is expected to be low and there is no toxic potential when ingested at levels estimated by the agency."*

The FDA said it also reviewed the results of analyses of several batches of pearlescent pigments and determined that they complied with the specifications in the new regulation.

On the particular issue of iron salt contaminants, the FDA referred to the manufacturing process of the pearlescent pigments, noting that the starting materials for the pigments included soluble iron salts, however, the manufacturing process incorporated a heating (calcination) step at temperatures up to 900C – at which point the starting iron salts are converted into iron oxide.

As the objection to the submission *"did not provide any factual information to support the claim,"* the FDA has pressed ahead with the new ruling, and drug firms are now free to colour their products as they wish - although the critics have not been silenced.

Consumer health advocate Mike Adams, who is fiercly critical of the FDA's decision, stated: *"the chemicals have never been tested in combination with prescription drugs to see if there are synergistic toxicities that may not be readily apparent."*

"When an industry's products harm people more than they help, it will inevitably turn to hype, propaganda and cosmetic appeal in order to manipulate consumer perception."

Indeed, many would agree, seeing the controversial decision as a worrying sign that drug marketing has finally been allowed to go too far.

However, the FDA refused In-PharmaTechnologist's request to comment any further on the matter.

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